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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,909	11/23/2001	George Jackowski	2132.090	7376

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,909	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claim 1 has been amended as requested in the amendment filed on July 11, 2005. Following the amendment, claims 1 and 39-46 are pending in the instant application.

Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made by original presentation in Paper mailed on May 28, 2004.

Claim 1 is under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on July 11, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claim 1, as amended stands rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 6 of Paper mailed on January 31, 2005.

Applicant traverses the rejection on the premises that the biological significance of the instant claimed fragment 2-14 of SEQ ID NO: 1 is well known in the art and is based on the biological role of the complement system (page 16 of the Response). Applicant further submits that "the complement system is associated with Alzheimer's disease, cognitive disorders and Syndrome-X" (middle at page 17) and states that "the claimed peptide (amino acid residues 2-14 of SEQ ID NO: 1) is useful for diagnosis and treatment of Alzheimer's disease since it was found to evidence a link to Alzheimer's disease (an "asserted utility"), see page 18 of the Response. Applicant's arguments have been fully considered but are not persuasive for the following reasons.

There is no argument that the role of complement system is well described in the art. Moreover, the art teaches that complement C3 precursor protein could be potentially associated with Alzheimer's disease, as well as many other proteins and precursors of these proteins are described as being associated with Alzheimer's disease. However, the issue at hand remains that the instant specification fails to provide any evidence of record or rely on any prior art disclosure to support the assertion that this instant claimed fragment 2-14 of SEQ ID NO: 1 is useful for diagnosis or treatment of Alzheimer's disease, as stated by Applicant. The Examiner maintains the position that contrary to Applicant's statement, neither prior art nor the instant specification

"explain[s] the biological significance of the claimed biopolymer marker in the development of Alzheimer's disease" (page 22 of the Response). First, there appears to be no information available in the publications of record regarding the role of the instant fragment 2-14 of SEQ ID NO: 1 with respect to Alzheimer's disease, and, second, the finding of this fragment in limited amount of serum samples treated according to the provided protocol alone does not allow a conclusion of its "biological significance in development of Alzheimer's disease". One skilled in the art readily appreciates that serum samples contain a plurality of proteins and the isolation of one of these protein cannot alone serve as demonstration of finding of a marker for Alzheimer's disease. As fully explained in the previous communication of record, a proper biological marker is not the one that is "identified in a body fluid sample from an Alzheimer's patient" but rather the one that is also not found in a body fluid sample from a control patient free of Alzheimer's disease as well as from a patient suffering from another, not Alzheimer's, disease. The instant specification also provides no evidence of record that this instant claimed biopolymer marker, which is a peptide 2-14 of SEQ ID NO: 1, could be used for treatment of Alzheimer's disease, as asserted by Applicant.

Further, to clarify the Examiner's position, it was never disputed that the claimed protein 2-14 of SEQ ID NO: 1 could be potentially linked to Alzheimer's pathology since it has been found in serum sample of a patient suspected of having Alzheimer's disease (the state of the art remains clear and sound that the definitive diagnosis of Alzheimer's disease could be made only during postmortem examination of patient's brain, see reasons of record in previous office actions). However, the worker of skill in the art readily appreciates that in order to serve as a marker, the claimed peptide must be either present or absent or present at altered levels in tissue

sample in order to be useful as a diagnostic tool. At page 23 of the Response, Applicant submits that "Figure 1 shows that the claimed peptide appears to be down-regulated in Alzheimer's disease; clearly indicating the relationship between the claimed peptide and Alzheimer's disease" (emphasis added). Based on the information provided in Figure 1, a skilled artisan could reasonably conclude that the instant claimed peptide "appears to be down-regulated in Alzheimer's disease"; however, this alone is clearly not sufficient to assign a role of a marker or a tool for treatment of Alzheimer's for the claimed peptide.

Applicant's asserted utility for the claimed protein 2-14 of SEQ ID NO: 1 constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). While an assay that detects the presence of an agent that has a stated correlation to the onset of a specific disease condition would be considered a "substantial utility" in the context of identifying potential candidates for preventive measures, in the instant case, the claimed peptide is suitable only for additional research.

Thus, for the reasons set forth, the claimed isolated biopolymer marker does not a real-world use and does not meet the utility requirements under 35 U.S.C. § 101.

Claim Rejections - 35 USC § 112

7. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Applicant's arguments presented on pages 25-38 have been fully considered but are not persuasive because the instant enablement rejection does not stand separately but is a part of rejection under 35 U.S.C. § 101. Briefly, because the claimed invention is not supported by either a clear asserted utility or a well

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

August 24, 2005